



Medical Necessity Criteria for Transdermal Patch (Emsam)

Drug Class - Monoamine oxidase inhibitor (MAOI) antidepressants. This drug class includes three oral medications: phenelzine (Nardil), tranylcypromine (Parnate, generics), and isocarboxazid (Marplan); and a transdermal patch, selegiline (Emsam).

Background - After evaluating the relative clinical and cost effectiveness of the MAOI antidepressants, the DoD P&T Committee recommended that selegiline transdermal patch (Emsam patch) be designated as non-formulary. This recommendation has been approved by the Director, TMA.

Effective Date: 1 August 2007

Patients currently using Emsam patch may wish to ask their doctor to consider a formulary alternative.

Special Notes:

1. Active duty cost share always \$0 in all points of service for all three tiers; Active duty cost share always \$0 in all points of service for all three tiers; TRICARE does not cover non-formulary medications for active duty service members unless they are determined to be medically necessary.
2. MTFs will be able to fill non-formulary requests for non-formulary medications only if both of the following conditions are met: 1) a MTF provider writes the prescription, and 2) medical necessity is established for the non-formulary medication. MTFs may (but are not required to) fill a prescription for a non-formulary medication written by a non-MTF provider to whom the patient was referred, as long as medical necessity has been established.

Medical Necessity Criteria for Transdermal Patch (Emsam)

The non-formulary cost share for Emsam may be reduced to the formulary cost share if the patient meets any of the following criteria:

1. Use of ALL of the formulary alternatives is contraindicated (e.g., due to hypersensitivity).
2. The patient has experienced or is likely to experience significant adverse effects from ALL of the formulary alternatives.
3. Use of ALL of the formulary alternatives has resulted in therapeutic failure.
4. The patient previously responded to Emsam patch and changing to a formulary alternative would incur an unacceptable clinical risk (e.g., patient is currently stabilized on therapy and changing to a formulary alternative would present a risk of destabilization).
5. The patient is unable to take oral medications.

Criteria approved through the DoD P&T Committee process February, 2007

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TRICARE Pharmacy Program Medical Necessity Form for Emsam Patch



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This form applies to the TRICARE Pharmacy Program (TPharm). The medical necessity criteria outlined on this form also apply at Military Treatment Facilities (MTFs). The form must be completed and signed by the prescriber.

- Monoamine oxidase inhibitor (MAOI) antidepressants on the DoD Uniform Formulary include phenelzine (Nardil), tranylcypromine (Parnate, generics), and isocarboxazid (Marplan). **Emsam (selegiline transdermal patch) is non-formulary, but available to most beneficiaries at the non-formulary cost share.** Formulary antidepressants include Effexor / Effexor XR (venlafaxine); citalopram, fluoxetine, paroxetine immediate release, and sertraline; bupropion immediate/sustained release; mirtazapine; and nefazodone.
- You do NOT need to complete this form in order for non-active duty beneficiaries (spouses, dependents, and retirees) to obtain Emsam patch at the non-formulary cost share. The purpose of this form is to provide information that will be used to determine if the use of a non-formulary medication instead of a formulary medication is medically necessary. If Emsam patch is determined to be medically necessary, non-active duty beneficiaries may obtain it at the formulary cost share.
- Active duty service members may not fill prescriptions for a non-formulary medication unless it is determined to be medically necessary. There is no cost share for active duty service members at any DoD pharmacy point of service.

MAIL ORDER and RETAIL	<ul style="list-style-type: none"> • The provider may call: 1-866-684-4488 or the completed form may be faxed to: 1-866-684-4477 • The patient may attach the completed form to the prescription and mail it to: Express Scripts, P.O. Box 52150, Phoenix, AZ 85072-9954 or email the form only to: TpharmPA@express-scripts.com 	MTF	<ul style="list-style-type: none"> • Non-formulary medications are available at MTFs only if both of the following are met: <ul style="list-style-type: none"> ○ The prescription is written by a military provider or, at the discretion of the MTF, a civilian provider to whom the patient was referred by the MTF. ○ The non-formulary medication is determined to be medically necessary. • Please contact your local MTF for more information. There are no cost shares at MTFs.
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Step 1 Please complete patient and physician information (Please print)

1	Patient Name: _____ Address: _____ Sponsor ID #: _____ Date of Birth: _____	Physician Name: _____ Address: _____ Phone #: _____ Secure Fax #: _____
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Step 2 1. Please explain why the patient cannot be treated with any of the formulary alternatives:

Please indicate which of the reasons below (1-5) applies to each of the formulary alternatives listed in the table. You **MUST** circle a reason **AND** supply a written clinical explanation specific for **EACH** formulary alternative.

Formulary Alternative	Reason	Clinical Explanation
Phenelzine (Nardil)	1 2 3 4 5	
Tranylcypromine (Parnate, generics)	1 2 3 4 5	
Isocarboxazid (Marplan)	1 2 3 4 5	

Note: dietary restrictions apply to the two highest strengths of the patch, as well as the oral MAOI antidepressants.

Acceptable clinical reasons for not using a formulary alternative are:

1. The formulary alternative is contraindicated (e.g., due to a hypersensitivity reaction).
2. The patient has experienced or is likely to experience significant adverse effects with the formulary alternative.
3. The formulary alternative resulted in therapeutic failure.
4. The patient previously responded to Emsam patch and changing to a formulary MAOI antidepressant would incur an unacceptable clinical risk (e.g., patient is currently stabilized on therapy and changing to a formulary MAOI antidepressant would present a risk of destabilization).
5. The patient is unable to take oral medications.

Step 3 I certify the above is correct and accurate to the best of my knowledge. Please sign and date:

3

Prescriber Signature

Date

Latest revision: April 2007